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(54) **An insert for a conduit**

(57) There is disclosed an insert (2) for a conduit (4) adapted to effect helical flow in the conduit (4) comprising a longitudinally extending member having a helical formation.

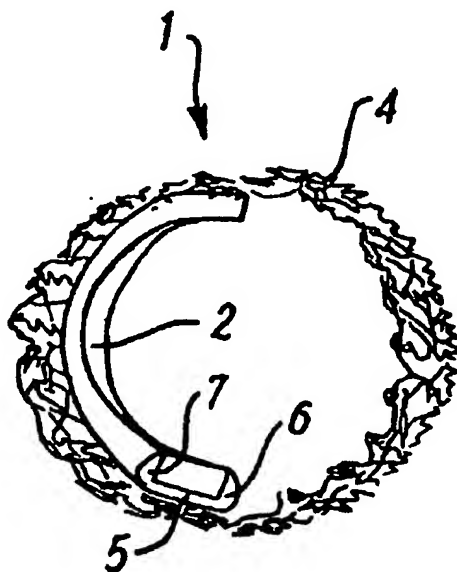


FIG. 2

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Description

[0001] This invention relates to an insert for a conduit, and especially, but not solely, an insert to modify flow in blood flow tubing such as veins and arteries of the human or animal body for the purpose of effecting helical flow therein.

[0002] WO 00/38591 discloses modified blood flow tubing and stents for use in blood flow tubing with spiral configurations that induce spiral (or helical) flow in the tubing. There is evidence that spiral flow has a beneficial effect in reducing turbulence and dead flow spots in the tubing. It is believed that turbulence and dead flow spots contribute to the build up of plaque, or narrowing of blood vessels, which can result in blockage at or downstream of the tubing or stent.

[0003] Stents are commonly used to open up and/or maintain open constricted arteries, and, as disclosed in WO 00/38591, can incorporate helical formations to induce the desired spiral flow.

[0004] However, stents are already of some complexity, arising from the need to introduce them in compact form for easy passage through the artery to the target site, then to expand them to open the restriction or to fit a previously opened restriction. Introducing a helical flow inducing configuration is an added complication.

[0005] In accordance with a first aspect of the present invention, there is provided an insert for a conduit, the insert being adapted to effect helical flow in the conduit and comprising a longitudinally extending member defining at least a portion of a helix.

[0006] The terms "helix", "helical" and "spiral" as used herein cover the mathematical definition of helix and helical and any combination of the mathematical definitions of helical and spiral.

[0007] The longitudinally extending member may be, in cross-section, flat. However, it may have an inwardly extending portion that extends inwardly of the helix and also extends lengthwise along the member. The inwardly extending portion may extend along an edge of the longitudinally extending member, or may extend, lengthwise, intermediate the edges of the longitudinally extending member.

[0008] The longitudinally extending member may have two inwardly extending portions, and preferably, at least one may extend lengthwise along an edge of the longitudinally extending member.

[0009] Preferably, the inwardly extending portion, or portions, is movable between the inwardly extended position and a collapsed position. This has the advantage that where the insert is used in a stent, the portion(s) can be moved to the collapsed position when the stent is collapsed to facilitate insertion of the stent. Typically, the inwardly extending portion, or portions, are biased towards the extended position. Hence, when the stent is expanded, the inwardly extending portion(s) move when permitted to the extended position. Preferably, the biasing of the inwardly extending portions to the extended position is enabled by an elastic deformation of the inwardly extending portion(s) to the collapsed position(s). For example, the inwardly extending portion may be elastically compressible or elastically deflectable to the collapsed position.

[0010] Typically, the longitudinally extending member is adapted to be attached to an internal side wall of a conduit, such as a stent, stent graft or graft. In this example the longitudinally extending member defines a helix or helix/spiral combination around the longitudinal axis of the conduit.

[0011] Alternatively, it is possible that the longitudinally extending member may be so configured in relation to a conduit for which it is adapted that its cross-section at any position along the conduit is substantially on a diameter of the conduit cross-section.

[0012] The insert may be adapted to lodge inside a vein or artery of the human or animal body, and may be adapted to lodge inside a stent in a vein or artery of the human or animal body, or a graft therein.

[0013] The insert may have a pitch, in relation to its length, such that one end is angularly displaced from the other by less than one revolution. Typically, the revolution of the total length of the insert is at least 50%, and preferably at least 70% of one revolution. If multiple inserts are provided in the conduit, the revolution may be the combined total of the revolution of each insert.

[0014] Preferably, where the insert is for use in the human or animal body, the insert comprises a biocompatible material, if it is to be left for any length of time.

[0015] In one example of the invention, the insert may also be biodegradable, so that it can serve for a predetermined period of time without needing to be removed.

[0016] In accordance with a second aspect of the present invention, there is provided a stent comprising a tubular body member and an insert mounted within the body member, the insert comprising a longitudinally extending member defining at least a portion of a helix.

[0017] Preferably, the tubular body member is movable between a collapsed position, during insertion of the stent, and an expanded position, when the stent is located in the desired position.

[0018] Typically, the longitudinally extending member has an inwardly extending portion that extends inwardly away from the internal side-walls of the tubular body section. Preferably, the inwardly extending portion is movable to a collapsed position.

[0019] In one example of the invention, the stent comprises a single insert. However, in other examples of the in-

vention, the stent may comprise two or more inserts, typically, on the same cross-section of the tubular body member.

[0020] Typically, the portion of a helix defined by the longitudinally extending member is at least 50% of one revolution, and preferably at least 70% of one revolution. However, if multiple inserts are provided, the total portion of a helix defined by all the longitudinally extending members may be at least 50%, and preferably, at least 70% of one revolution.

[0021] Preferably, the insert has two inwardly extending portions extending along the length of the longitudinally extending member. However, alternatively, the insert may have only one inwardly extending portion extending along the length of the longitudinally extending member.

[0022] Inserts for a conduit in accordance with the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a side view of a stent with a first insert;

Figure 2 is an end view of the stent of Figure 1;

Figure 3 is a cross-section view of the first insert in an open position;

Figure 4 is a cross-section view of the first insert in a collapsed position;

Figure 5 is a cross-sectional view of a second insert;

Figure 6 is a cross-sectional view of a third insert;

Figure 7 is a cross-sectional view of a fourth insert in an extended position;

Figure 8 is a cross-sectional view of the fourth insert in a collapsed position;

Figure 9 is a schematic diagram showing relative positions of a cuff and a stent in a carotid artery of a pig;

Figure 10 is a section along the line CC of Figure 9 of a right carotid artery fitted with a prior art stent; and

Figure 11 is a section along the line CC of Figure 9 of a left carotid artery of a pig fitted with the stent shown in Figures 1 and 2.

[0023] Figures 1 and 2 show a stent 1 having a main body 4 which is formed from a wire mesh material. Alternatively, the stent 1 could be formed from a tube with interruptions or a laser cut tube providing an expandable homogeneous structure. Attached to the internal side wall of the body 4 is an insert 2 which defines a helix.

[0024] The insert 2 is typically manufactured from a biocompatible material, such as polyurethane, and may be attached to the internal side wall of the body 4 by injection moulding, insert moulding, glue or melting base portion 5 of the insert 2 onto the body 4 such that after cooling, the mesh structure of the body 4 is entrained with the base portion 5 of the insert 2.

[0025] A cross-sectional view of the insert 2 is shown in Figure 3 where it can be seen that insert 2 also includes two fins 6, 7 extending from the base portion 5 at opposite edges of the base portion 5. It will be noted from Figures 1 and 2 that the fins 6, 7 extend along the length of the insert 2 and extend inwardly from the internal side walls of the main body 4.

[0026] In use, the stent 1 is inserted into a blood vessel in the human or animal body in a collapsed configuration and after it is located in the correct position, it is expanded to engage with the side walls of the blood vessel to locate the stent 1 in the desired position. Typically, the stent 1 is inserted on a balloon catheter with the stent 1 in the collapsed configuration around the collapsed balloon of the catheter. When the stent 1 is in the correct position in a blood vessel, the balloon is then inflated by pumping fluid into the balloon through the catheter. The expansion of the balloon expands the stent 1 into engagement with the internal side walls of the blood vessel. The configuration of the stent 1 shown in Figure 1 is in the expanded position. That is, the configuration after it is engaged with the internal side walls of the vessels by expanding the balloon of a balloon catheter, and the balloon catheter is removed.

[0027] Alternatively, the stent 1 may be formed from an expansible material that "self-expands" into position, for example, by thermal mending properties.

[0028] When the stent 1 is collapsed onto the balloon of the catheter, or the stent delivery system, the Insert 2 is designed such that the fins 6, 7 are bent inwardly so that the fins of the insert collapse so as to reduce the volume occupied by the insert 2 when the stent 1 is in the collapsed configuration. This is illustrated in Figure 4 where it can be seen that fin 7 bends inwardly to overlie the base 5 and fin 6 bends inwardly to overlie the fin 7. This feature is enabled by appropriate design of the base portion 5 and fins 6, 7 and a suitable choice of material for the insert 2. Typically, this is an elastically deformable material, such as a suitable plastic material, for example, polyurethane. Hence, as the collapsing is an elastic deformation of the insert 2, the fins 6, 7 automatically return to the non-collapsed position, shown in Figure 2, after expansion of the stent 1 and removal of the balloon catheter.

[0029] After insertion and placement in the desired blood vessel, the insert 2, due to its helical shape, acts on blood flowing through the stent 1 to generate a spiral flow component in the blood.

[0030] The length of the stent 1 is to a large extent dictated by enabling sufficient flexibility to ensure that the stent 1 can be inserted into the desired location in the human or animal body or the length of the narrowed artery requiring or able to be supported by the stent. That is, the length may depend on the length of the vessel needing treatment. Accordingly, the stent 1 typically has a length in the region of 10 mm to 100 mm. For certain vessels this may be

normally approximately 20 mm to 40 mm in length. In order for the insert 2 to generate spiral flow of blood passing through the stent 1, the helix angle of the helix defined by the insert 2 must not be too high. Therefore, to generate an effective spiral flow component, the insert 2 typically defines only a portion of one revolution of the helix that it defines. Preferably, this is at least 50% of one revolution and most preferably greater than 70% of one revolution. However, the effect may be enhanced by using a number of inserts 2 within the stent 1.

[0031] When blood flows through the stent 1, the helical formation of the insert 2 will tend to generate a spiral flow formation in the blood exiting from the stent 1. This spiral flow tends to reduce turbulence and promote better flow of blood within the blood vessels of the human or animal body into which it is inserted.

[0032] This has been supported by experimental results. A pig had the stent 1 inserted, on a balloon catheter delivery system, in the left carotid artery and a cuff applied surgically to the artery downstream of the stent. A prior art stent identical to the stent 1, except for the absence of the insert 2, was inserted in a similar manner in the right carotid artery and a cuff was also applied surgically to the right carotid artery downstream of the prior art stent. The stent placements and the downstream cuffs were checked by intra-arterial contrast injection under X-ray (angiography). The cuffs 41 applied a moderate stenosis to each of the right and left carotid arteries 40 downstream of the stent. The cuffs 41 each produced a stenosis of approximately 75%. The relative positions of the stents in the carotid arteries 40 and the cuffs 41 are shown in Figure 9.

[0033] After two weeks the left and right carotid arteries 40 were explanted and examined grossly and histologically. The three sites along the carotid arteries 40 which were compared for the right and left carotid arteries 40 are indicated by the lines AA, BB and CC in Figure 9. At each site AA, BB, CC the intimal and medial thickness and the intimal/medial thickness ratio were determined. The results are shown in Table 1 below and sections at site CC for the right and left carotid arteries are shown in Figures 10 and 11, respectively.

Table 1

Pig Artery	Section	Intimal (μm)	Medial (μm)	I+M (μm)	I/M (%)
Left Carotid	AA	35.6	649.8	685.4	5.5
	BB	6.0	362.2	368.2	1.2
	CC	5.7	250.4	240.7	2.7
Right Carotid	AA	48.7	680.8	729.6	7.2
	BB	52.5	628.7	681.1	8.4
	CC	347.3	387.5	734.9	89.7

[0034] A comparison of Figures 10 and 11 shows that there was extensive intimal thickening in the distal cuff of the right carotid artery (i.e. the artery with the prior art stent) but little intimal thickening in the distal cuff of the left carotid artery (i.e. the artery with the stent 1). This is supported quantitatively by Table 1, which shows that intimal/medial thickness ratio at location CC was 89.7% for the right carotid artery, but only 2.7% for the left carotid artery. In addition, it can be seen from Figure 10 that there was also loss of lumen of the right artery at site CC. While Figure 11 shows that there was no loss of lumen of the left artery at site CC.

[0035] As an alternative to attaching the insert 2 directly to the body 4, it is also possible that the insert 2 may be attached to a flexible material, such as a membrane, and that the flexible material is then attached to the inside and/or outside of the body 4. For example, the flexible material may be a woven, knitted or spun polyester material, polyurethane material or extended PTFE material, and may be in the form of a tube which locates within the body 4 and is attached to the body 4 by a suitable means, such as adhesive or by stitching. The flexible material may be porous.

[0036] Although in the stent 1 only one insert 2 is used, it is possible that multiple inserts may be used in either end-to-end and/or side-by-side relationship within the body 4. Where multiple inserts are used, the total portion of the helix defined by all the inserts is typically greater than 50% and preferably greater than 70%. This means that any one insert may define a portion of a helix that is less than 50%.

[0037] Figure 5 shows a second example of an insert 10 that includes a base portion 11 with a fin 12 extending from one edge of the base portion 11. As with the insert 2, the fin 12 extends along the length of the insert 10.

[0038] Figure 6 shows a third example of an insert 20 that includes a base portion 21 with a fin 22 extending centrally from the base portion 21. As with the inserts 2, 10 the fin 22 extends along the length of the insert 20.

[0039] Figures 7 and 8 show a fourth example of an insert 24 that has a fin 23 formed from an elastically compressible foam material 25, such as a polyurethane foam. Figure 7 shows the insert 24 with the fin 23 in the extended position and Figure 8 shows the insert 24 with the foam material 25 compressed so that the fin 23 is collapsed.

[0040] The inserts 10, 20, 24 may be used in the stent 1 in the same manner as the insert 2.

[0041] The helical formations 2, 10, 20, 24 may each have a pitch, in relation to their length, such that one end is angularly displaced from the other by at least 50% of one revolution and preferably at least 70% of one revolution. This is found to impart favourable spiral flow to flow in a vein or artery, eliminating, or at least reducing, turbulence and dead spots with reduction of plaque formation.

[0042] For helical formations 2, 10, 20, 24 intended to remain on more than just a temporary basis, a biocompatible material will be selected, and a smooth structure with rounded ends will be preferred so as not to introduce any turbulence into the flow.

[0043] The use of stents as described is clearly not restricted to blood flow tubing. Other tubing - including external blood flow, eg. dialysis and heart-lung machine tubing, as well as tubing and pipework in industrial and civil engineering could also benefit from inserts, as described herein, and the invention, whilst it has been specifically described and illustrated with reference to blood flow tubing is to be regarded as of more general application.

Claims

1. An insert for a conduit the insert being adapted to effect helical flow in the conduit and comprising a longitudinally extending member defining at least a portion of a helix.
2. An insert according to claim 1, wherein the longitudinally extending member has an inwardly extending portion that extends inwardly of the helix and also extends lengthwise along the member.
3. An insert according to claim 2, wherein the inwardly extending portion extends along an edge of the longitudinally extending member.
4. An insert according to claim 2 or claim 3, wherein the longitudinally extending member comprises two inwardly extending portions, of which at least one extends along an edge of the longitudinally extending member.
5. An insert according to claim 2, wherein the inwardly extending portion extends lengthwise and intermediate the edges of the longitudinally extending member.
6. An insert according to any of claims 1 to 5, wherein the insert is adapted to lodge inside a vein or artery of the human or animal body, or a graft therein.
7. An insert according to any of claims 1 to 5, wherein the insert is adapted to lodge inside a stent in a vein or artery of the human or animal body, or a graft therein.
8. An insert according to any of the preceding claims, wherein the rotation of a helix is at least 50% of one revolution.
9. An insert according to claim 8, wherein the rotation of the helix is at least 70% of one revolution.
10. An insert according to any one of claims 1 to 9, wherein the insert is manufactured from a material comprising a biocompatible material.
11. An insert according to any one of claims 1 to 10, wherein the insert is manufactured from a material comprising a biodegradable material.
12. A stent comprising a tubular body section and an insert mounted within the body section, the insert comprising a longitudinally extending member defining at least a portion of a helix.
13. A stent according to claim 12, wherein the longitudinally extending member has an inwardly extending portion that extends inwardly away from the internal side-walls of the tubular body section.
14. A stent according to claim 13, wherein the inwardly extending portion is movable between the extended position and a collapsed position.
15. A stent according to claim 14, wherein the longitudinally extending member comprises an elastically compressible material.

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16. A stent according to any of claims 12 to 15, wherein the insert has two inwardly extending portions extending along the length of the longitudinally extending member.

5 **17.** A stent according to any of claims 12 to 16, wherein the portion of a helix defined by the longitudinally extending member is at least 50% of one revolution.

18. The stent according to claim 17, wherein the portion of the helix is at least 70% of one revolution.

10 **19.** A stent according to any of claims 12 to 18, wherein the insert is mounted within a flexible tubular material and the flexible tubular material is mounted on the body section.

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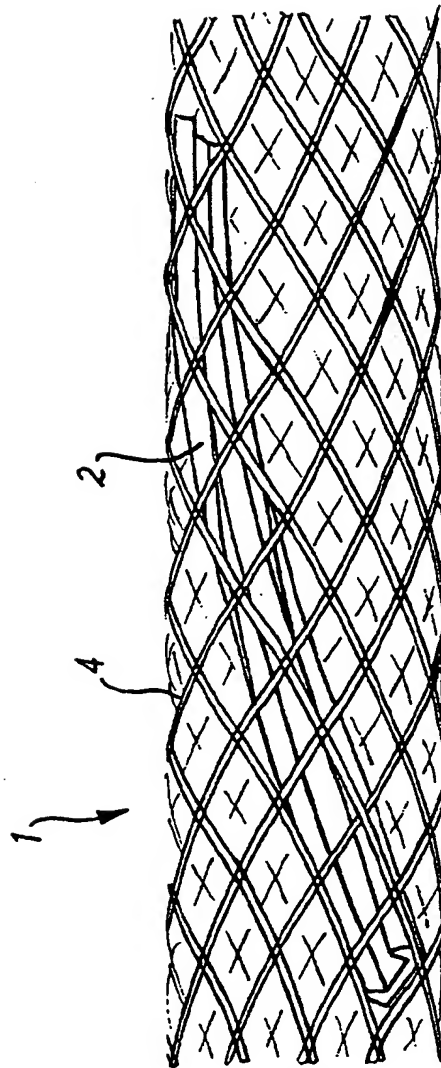


Fig. 1

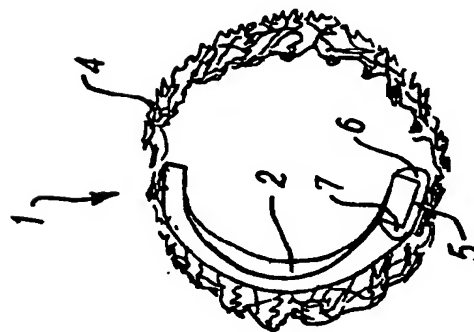


Fig. 2

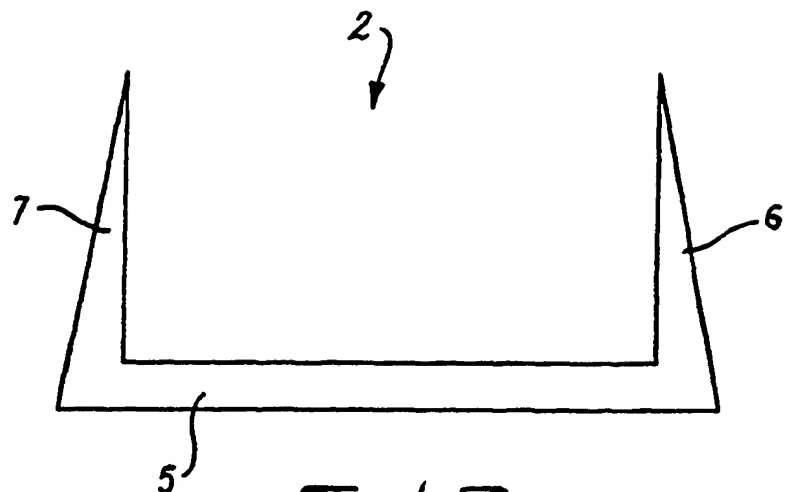


FIG. 3

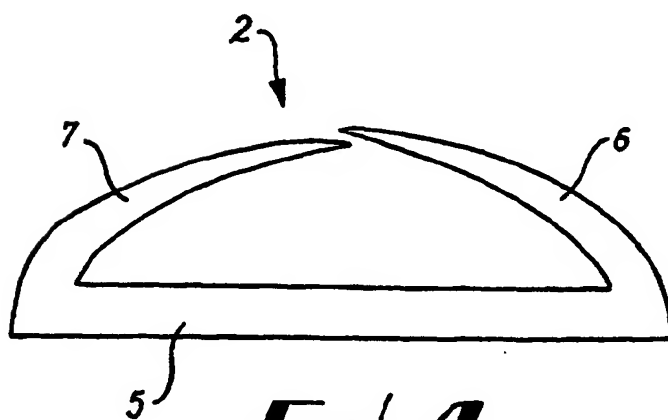
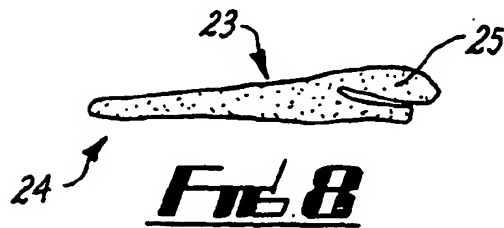
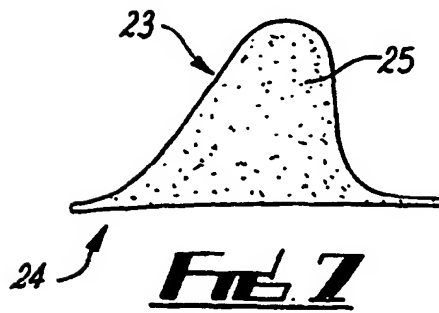
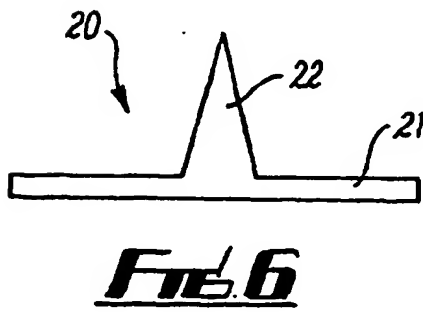
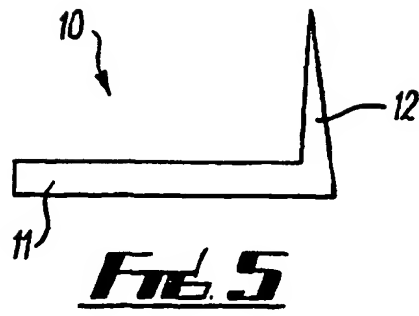


FIG. 4



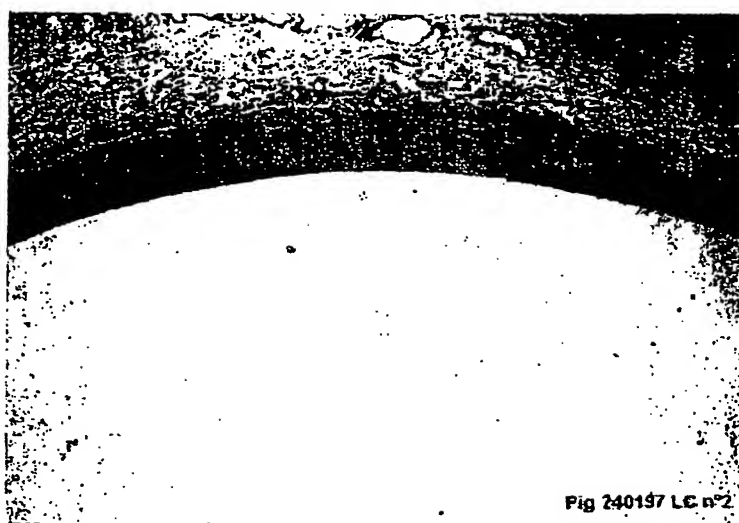
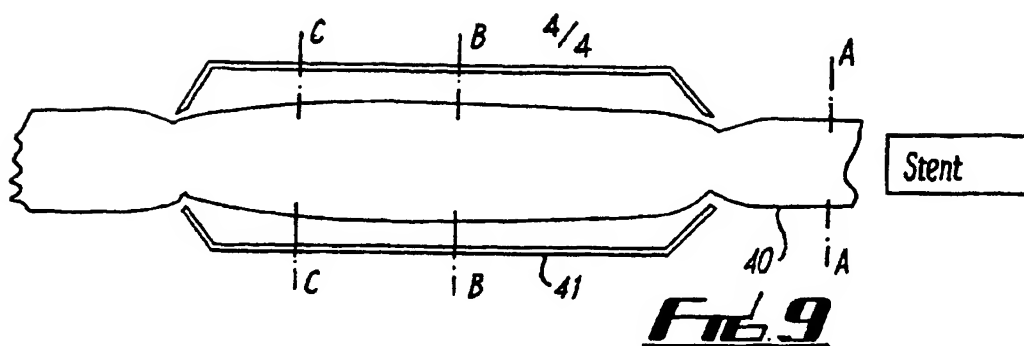


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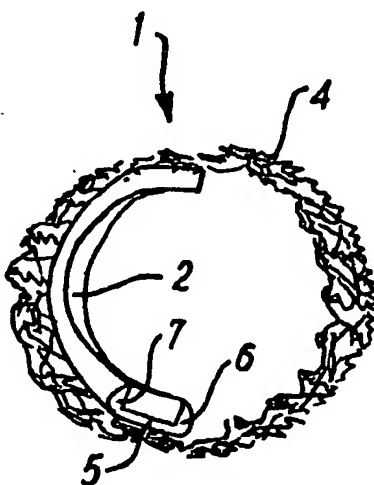


Fig. 2

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EUROPEAN SEARCH REPORT

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The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 3 March 2004	Examiner Neumann, E
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**ANNEX TO THE EUROPEAN SEARCH REPORT
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